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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/840,112	05/06/2004	Jaime Simon	3716444.00011	8566
24573	7590	08/03/2011		
K&L Gates LLP P.O. Box 1135 CHICAGO, IL 60690			EXAMINER SAMALA, JAGADISHWAR RAO	
			ART UNIT	PAPER NUMBER
			1618	
			NOTIFICATION DATE	DELIVERY MODE
			08/03/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

chicago.patents@klgates.com

Office Action Summary	Application No. 10/840,112	Applicant(s) SIMON ET AL.
	Examiner JAGADISHWAR SAMALA	Art Unit 1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 May 2011.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of Applicant's Amendments and Remarks filed on 05/09/2011.

- Claim 14 has been amended.
- Claims 1-14 are pending and presented for examination.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-8 and 10-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Kais et al (US 5,516,524) as evidence by Valorose et al (US 5,215,754).

Claims are drawn to a method for treating a fluid overload state in a host, comprising directly delivering to the intestinal tract an effective amount of a water-absorbent polymer, wherein the water-absorbent polymer is capable of absorbing at least 10 times its weight in physiological saline, wherein the polymer is enterically coated and the enteric coating is selected from at least one of hydroxypropylmethylcellulose.

Kais teaches a method for treating constipation with ingestible laxative compositions (removal of water and waste) comprising polycarbophil or calcium polycarbophil (Abstract, Col. 1 line 5-46, Col. 4 line 59-63). The solid dose forms include

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tablets, capsules, hard and soft shelled capsules, gel capsules with dry ingredients (powder/bead-Col. 4 line 3-6), wafer, food forms and powdered drink mixes (beads) (Col. 3 line 60-Col. 4 line 33). The forms can be coated to remain intact through the stomach and be dissolved before reaching the large intestine (enteric coating, direct delivery/activated to all parts of the intestine such as ileum (col. 5 line 22-29). The preferred coating material includes cellulose derivatives such as ethylcellulose, hydroxypropylmethylcellulose and mixtures thereof (col. 6 line 20-25). Kais teaches an example of an enterically coated tablet with ethylcellulose (enteric polymer) and the bulk fiber psyllium wherein Kais expressly teaches in the example that polycarbophil, calcium polycarbophil and other fibers can be substituted for the psyllium which they are immediately envisioned (Example IV). It is noted that the capacity of the polymer (e.g. polycarbophil) is inherent to the polymer which is at about 35 times or greater its weight in water meeting the claims (as addressed by Valorose above and evidenced by the instant specification Page 6 line 1-3).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kais et al (US 5,516,524) in view of Valorose et al (US 5,215,754) and Berger, deceased et al (US 4,470,975).

Claims are drawn to a method for treating a fluid overload state in a host, comprising directly delivering to the intestinal tract an effective amount of a water-absorbent polymer, wherein the water-absorbent polymer is capable of absorbing at least 10 times its weight in physiological saline, wherein the polymer is enterically coated and the enteric coating is selected from at least one of hydroxypropylmethylcellulose, wherein fluid overload state is congestive heart failure, cirrhosis of liver, nephrosis, ascites, renal disease, edema associated with chemotherapy.

Kais teaches a method for treating constipation with ingestible laxative compositions (removal of water and waste) comprising polycarbophil or calcium polycarbophil (Abstract, Col. 1 line 5-46, Col. 4 line 59-63). The solid dose forms include tablets, capsules, hard and soft shelled capsules, gel capsules with dry ingredients (powder/bead-Col. 4 line 3-6), wafer, food forms and powdered drink mixes (beads)

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(Col. 3 line 60-Col. 4 line 33). The forms can be coated to remain intact through the stomach and be dissolved before reaching the large intestine (enteric coating, direct delivery/activated to all parts of the intestine such as ileum (col. 5 line 22-29). The preferred coating material includes cellulose derivatives such as ethylcellulose, hydroxypropylmethylcellulose and mixtures thereof (col. 6 line 20-25). Kais teaches an example of an enterically coated tablet with ethylcellulose (enteric polymer) and the bulk fiber psyllium wherein Kais expressly teaches in the example that polycarbophil, calcium polycarbophil and other fibers can be substituted for the psyllium which they are immediately envisioned (Example IV). It is noted that the capacity of the polymer (e.g. polycarbophil) is inherent to the polymer which is at about 35 times or greater its weight in water meeting the claims (as addressed by Valorose above and evidenced by the instant specification Page 6 line 1-3).

Kais fails to teach fluid overload state such as congestive heart failure, renal diseases, or edema.

Berger teaches a method of removing fluid or edema by diverting water elimination from the renal route to the gastrointestinal route, and removing excess water from the body by the gastrointestinal tract of an animal by administering to said animal a polysaccharide such as dextran (see abstract, column 1, line 54-56. and column 10, lines 5-30). The cross-linked polysaccharides are capable of absorbing water with swelling, the water regain of the product being within the range of about 1 to 50 grams per gram of the dry gel product administered (see col. 4 lines, 34-59). The method also includes treatment for diseases characterized by an abnormal excess accumulation of

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fluid within the body, such as, congestive heart failure, cirrhosis of liver, nephrosis, and other renal diseases associated with fluid retention (col. 1 line 63+). Additionally disclosure includes that the insoluble cross-linked polysaccharide polymer may be ingested by the patient and during passage of these substances through the digestive system, water is absorbed or bound tremendously and finally along with bound water, urea in the lumen of the gastrointestinal system is then eliminated by passage from the alimentary canal in the normal manner.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the Berger's teaching into Kais's enteric coated solid dosage forms. The person of ordinary skill in the art would have been motivated to make those modifications because, Kais teaches that the coating material selected to coat the active ingredient remains largely intact through the stomach, thereby avoiding the gastric disturbances and is dissolved/melted/digested before reaching the large intestine so that the active ingredient is available for use (col. line 20-28). Therefore, one of ordinary skill in the art would have had a reasonable expectation of success because kais teaches that various single or multiple coatings can be employed to effective release of active agents into small intestine. For example, pH sensitive polymers suitable for use are selected from the groups consisting of cellulose acetate phthalate, polymethacrylic acid polymers, and mixtures thereof.

Conclusion

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAGADISHWAR SAMALA whose telephone number is (571)272-9927. The examiner can normally be reached on 8.30 A.M to 5.00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571)272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jake M. Vu/
Primary Examiner, Art Unit 1618

/J. S./
Examiner, Art Unit 1618

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